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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,034	07/05/2000	Xin-Xing Gu	NIH142.001C1	4610

7590

03/26/2002

Nancy W Vensko  
Knobbe Martens Olson & Bear LLP  
620 Newport Center Drive  
Sixteenth Floor  
Newport Beach, CA 92660-8016

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/610,034

Applicant(s)

GU ET AL.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002 and 23 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-34 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 39-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6-34 and 39-47 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicants' Information Disclosure Statement received January 4, 2002, paper 11 is acknowledged.
2. Applicants' amendment A received January 4, 2002, paper 12 is acknowledged. Claims 1-4 and 6-10 were amended. Claims 11-34 are withdrawn from consideration. Claim 5, 35-38 were canceled. New claims 39-47 were added.
3. Currently claims 1-4, 6-34 and 39-47 are pending.
4. Claims 1-4, 6-10 and 39-47 are under consideration.

### ***Prior Citations of Title 35 Sections***

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

### ***Drawings***

6. The formal drawings submitted January 23, 2002 are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 498.

### ***Objection Moot***

7. Objection to claim 5 made in paragraph 6 of the office action mailed July 31, 2001 is moot in view of cancellation of the claim.

### ***Rejection Withdrawn***

8. Rejection of claims 1-10 and 35-38 under 35 USC 112 first paragraph made in paragraph 7 of the office action mailed July 31, 2001 is withdrawn in view of applicants' amendment.
9. Rejection of claims 1-10 and 35-38 under 35 USC 103 made in paragraph 8

of the office action mailed July 31, 2001 is withdrawn in view of applicants' amendment.

***New Ground for Rejection***

***Rejections - 35 USC § 103***

10. Claims 1-4, 6-10 and 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaneechoutte et al. (Journal of Clinical Microbiology, Vol. 28, No.2, pp. 182-187, 1990.) in view of Gu et al. (U.S. Patent Number 6,207,157) and Campagnari et al. (Microbial Pathogenesis, Vol. 8, pp. 353-362, 1990).

Claims are drawn to an immunogenic composition comprising lipooligosaccharide isolated from *Moraxella catarrhalis*.

Vaneechoutte et al. teach immunogenic compositions comprising lipooligosaccharide isolated from *Moraxella (Barnhamella) catarrhalis* (see abstract and material and method page 182). Vaneechoutte et al. do not teach detoxification to produce dLOS or protein as immunogenic carrier. However, Gu et al. teach a conjugate vaccine for *Haemophilus influenzae* comprising lipooligosaccharide (LOS) from which esterified fatty acids have been removed conjugated to an immunogenic carrier. The vaccine is useful for prevention of otitis media and respiratory infections in mammals (see abstract). They also teach a LOS from which esterified fatty acids have been removed from lipid A to form a detoxified LOS (dLOS), and an immunogenic carrier (a protein) covalently linked thereto (see claims 1 and 2). They further teach, wherein immunogenic carrier protein is selected from the group consisting of tetanus toxin/toxoid, a high molecular weight (HMP) isolated from nontypeable *Haemophilus influenzae*, diphtheria toxin/toxoid, detoxified *P. aeruginosa* toxin A, cholera toxin/toxoid,

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pertussis toxin/toxoid and more (see claim 3). They too teach alum as an adjuvant (see claims 10-11). They also teach linker compounds such as adipic acid dihydrazide,  $\epsilon$ -aminohexanoic acid, chlorohexanol dimethyl acetal, D-glucuronolactone and p-nitrophenylethyl amine (see claims 5-7).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to apply the method of preparing a conjugate vaccine from detoxified LOS taught by Gu et al. to the isolated lipooligosaccharides of Vaneechoutte et al. to obtain the instant disclosure. Given the art-recognized fact that lipooligosaccharide epitopes shared among gram negative non-enteric mucosal pathogens such as *Haemophilus influenzae* and *Moraxella catarrhalis* (Campagnari et al., see abstract, title and introduction) and the fact that Gu et al. teach the same method steps as the claimed invention for production of a conjugate vaccine for *Haemophilus influenzae*. One having ordinary skill in the art would have been motivated by expectation of success and the attainment of a better composition comprising LOS from *Moraxella catarrhalis* to make an immunogenic composition from *Moraxella catarrhalis*.

### ***Conclusion***

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL** necessitated by applicants' amendments. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 - 3/20/02

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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MARK NAVARRO  
PRIMARY EXAMINER